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मानक

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IS 12901 (1990): ENT Surgery Instruments - Laryngeal Fine Grasping Forceps, Crocodile Jaws, Straight [MHD 4: Ear, Nose and Throat Surgery Instruments]



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Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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Indian Standard

**ENT SURGERY INSTRUMENTS — LARYNGEAL
FINE GRASPING FORCEPS, CROCODILE JAWS,
STRAIGHT — SPECIFICATION**

भारतीय मानक

**कान, नाक तथा गला शल्य चिकित्सा यंत्र — कंठ में सजबूत पकड़ के लिए सीधो एवं गहरी
नालियों के क्रोकोडायल जबड़े वाली चिमटी — विशिष्ट**

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**BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002**

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards after the draft finalized by the Ear, Nose and Throat Surgery Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

ENT SURGERY INSTRUMENTS — LARYNGEAL FINE GRASPING FORCEPS, CROCODILE JAWS, STRAIGHT — SPECIFICATION

1 SCOPE

1.1 This standard covers dimensional and other requirements for laryngeal, fine grasping forceps, crocodile jaws, straight used in ENT surgery.

2 REFERENCES

2.1 The following Indian Standards are necessary adjuncts to this standard:

<i>IS No.</i>	<i>Title</i>
1501 (Part 1) : 1984	Method of vickers hardness test for metallic materials: Part 1 HV 5 to HV 100 (<i>second revision</i>)
2771 (Part 1) : 1977	Fibreboard boxes: Part 1 Corrugated fibreboard boxes (<i>first revision</i>)
3642 (Part 1) : 1990	Surgical instruments: Part 1 Non-cutting articulated type (<i>second revision</i>)
6603 : 1972	Stainless steel bars and flats

3 MATERIAL

3.1 The components of forceps shall be made of stainless steel conforming to Designation 30Cr13 of IS 6603 : 1972.

4 SHAPE AND DIMENSIONS

4.1 The shape and dimensions shall be as shown in Fig. 1.

4.2 Tolerances

4.2.1 The tolerances of linear dimensions shall be as follows:

- ±0.05 mm on dimensions up to 2.0 mm
- ±0.1 mm on dimensions above 2.0 mm and up to 5.0 mm
- ±0.2 mm on dimensions above 5.0 mm and up to 20.0 mm
- ±0.5 mm on dimensions above 20.0 mm and up to 50.0 mm
- ±1.0 mm on dimensions above 50.0 mm and up to 100.0 mm
- ±2.0 mm on dimensions above 100.0 mm

4.2.2 The tolerances on angular dimensions shall be as follows:

- ±1° for angles up to 10°
- ±2° for angles greater than 10°

4.2.3 The identical dimensions of two halves of the instrument shall not differ and the halves shall match with each other perfectly.

4.3 Joint

The joint shall be as specified in IS 3642 (Part 1) : 1990. The joint shall be rivetted.

4.4 Finger Loops

The finger loops shall be as specified in IS 3642 (Part 1) : 1990.

5 HEAT TREATMENT

5.1 The component parts of the forceps shall be heat treated under suitable conditions to give a hardness of 540 to 640 HV.

5.2 Mating surface of the same instrument, such as opposite jaws, blades and shanks shall not vary in hardness by more than 40 HV.

6 WORKMANSHIP

6.1 It shall be possible to close and reopen the instrument with two fingers and there shall be no play at the joint.

6.2 The maximum opening of the upper jaw shall correspond to the maximum opening of the finger loops, that is, when the finger loops are open to their maximum position, the upper jaw shall not move further to its maximum opening.

6.3 The jaws shall open and close fully (*see* Fig. 1) and freely. The jaw shall register accurately and shall close completely without any gap when the forceps is closed.

6.4 All the edges shall be rounded unless specified otherwise, and the edges of the working ends shall be sharp.

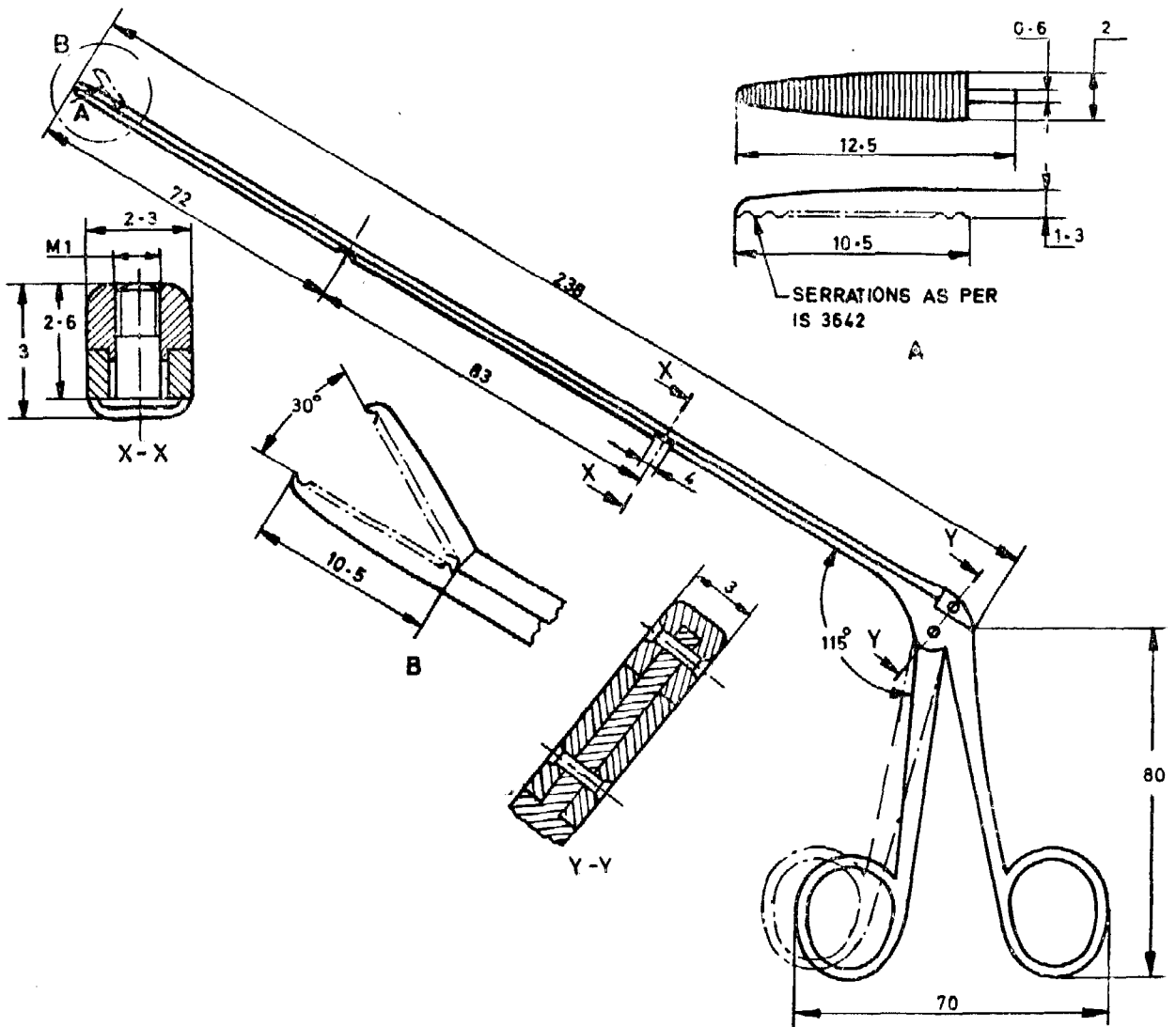
7 SURFACE CONDITION

7.1 General

All surfaces shall be free from pores, cracks, seams, burs, flaws, crevices and grinding marks. The instrument shall be supplied free from residual scale, acid, grease and grinding and polishing materials.

7.2 Surface Finish

The instrument shall have satin finish.



All dimensions in millimetres.

FIG. 1 LARYNGEAL FORCEPS, FINE GRASPING, CROCODILE JAWS, STRAIGHT

7.3 Passivation and Final Treatment

The instrument shall be treated by a suitable passivation process, for example, by electroplating or by treatment with 10 percent (v/v) nitric acid solution for not less than 30 minutes at a temperature of not less than 10°C and not exceeding 60°C. The instrument shall then be rinsed in water and dried in hot air.

NOTE — If the joint is lubricated, then the lubricant shall be non-corrosive and suitable for medical application according to Indian Pharmacopoeia.

8 TESTS

8.1 Hardness

The forceps shall be tested for hardness as specified in 5.1 in accordance with IS 1501 (Part 1) : 1984.

8.2 Flexibility

8.2.1 The jaws of the forceps shall be made to bite a double layer of wet blotting paper. The jaws shall have a clear impression of complete sharp edge on the blotting paper. The jaws of the forceps shall also be made to bite a piece of rubber sheet 1 mm thick and the finger loops closed as fully as possible [applying a force of about 1 Newton (1 kgf approx)]. The cutting edges shall be examined under a magnification of 10 X along the plane of the cutting edges for feathers, nicks, waviness, etc, and on release, the forceps shall not show any sign of damage or the upper jaw shall not become loose at its hinges.

8.3 Corrosion Resistance

The forceps shall be tested for resistance against corrosion both by copper sulphate test and boiling water test as given in 8.3.1 and 8.3.2.

The forceps shall not show any sign of corrosion after each test.

8.3.1 Copper Sulphate Test

8.3.1.1 Test solution

Copper (II) sulphate pentahydrate ($\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$)	4 g
Sulphuric acid (H_2SO_4) ($d = 1.84 \text{ g/ml}$)	10 g
Distilled or de-ionized water	90 ml

8.3.1.2 Apparatus

Glass or ceramic beaker.

8.3.1.3 Procedure

Immerse the instrument in the test solution contained in the beaker at room temperature for 6 minutes. Remove the instrument and wash it with distilled water or water of equivalent quality, or wipe it with wet cotton wool. Examine the instrument for evidence of copper deposits.

8.3.2 Boiling Water Test

8.3.2.1 Reagent

Distilled or de-ionized water.

8.3.2.2 Apparatus

Glass or ceramic beaker or suitable corrosion-resistant stainless steel vessel.

8.3.2.3 Preparation of Sample

Scrub the instrument using soap and warm

water, rinse thoroughly in water (8.3.2.1) and dry.

8.3.2.4 Procedure

Immerse the instrument in boiling water (8.3.2.1) in the beaker or vessel for at least 30 minutes. Subsequently, allow the instrument to cool for at least 1 hour in the water used for the test.

Then remove the instrument from the water and leave it exposed to the air for 2 hours. Rub the instrument vigorously with a dry cloth and examine it for the presence of blemishes.

9 MARKING

9.1 Marking on the Instrument

The instrument shall be legibly and indelibly marked with the indication of the source of manufacture, the letters 'SS' or the words 'Stainless Steel'.

9.2 Marking on Cartons

The cartons or package containing the forceps shall bear same markings as on the instrument. In addition, the carton or the box shall also be marked with the name of the instrument and any other information required.

10 PACKING

10.1 The instrument shall individually either be put in a polyethylene bag or wrapped in wax paper.

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BUREAU OF INDIAN STANDARDS

Headquarters :

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones : 331 01 31, 331 13 75

Telegrams : Manaksanstha
(Common to all Offices)

Regional Offices :

	Telephone
Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg NEW DELHI 110002	{ 331 01 31 331 13 75
Eastern : 1/14 C.I.T. Scheme VII M, V.I.P. Road, Maniktola CALCUTTA 700054	37 86 62
Northern : SCO 445-446, Sector 35-C, CHANDIGARH 160036	2 18 43
Southern : C.I.T. Campus, IV Cross Road, MADRAS 600113	41 29 16
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